

**TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS
USING A DUAL-LASER SCANNING SYSTEM**

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and apparatus for the treatment of presbyopia and the treatment and prevention of glaucoma using dual-beam scanning lasers.

2. Prior Art

Corneal reshaping, including a procedure called photorefractive keratectomy (PRK) and a new procedure called laser assisted in situ keratomileusis, or laser intrastroma keratomileusis (LASIK), has been performed by lasers in the ultraviolet (UV) wavelength of 193 - 213 nm. Commercial UV refractive lasers include ArF excimer lasers at 193 nm and other non-excimer, solid-state lasers, such as the one patented by the present inventor in 1992 (U.S. Patent No. 5,144,630). Precise, stable corneal reshaping requires lasers with strong tissue absorption (or minimum penetration depth) such that the thermal damage zone is at a minimum (less than few microns). Furthermore, accuracy of the procedure of vision correction depends on the amount of tissue removed in each laser pulse, in the order of about 0.2 microns. Therefore, lasers at UV wavelengths between 193 and 213 nm and at the mid-infrared wavelengths between 2.8 and 3.2 microns are two attractive wavelength ranges which match the absorption peak of protein and water, respectively.

The above-described prior arts are however limited to the use of reshaping the corneal surface curvature for the correction of myopia and hyperopia.

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1 A variation of farsightedness that the existing laser
2 surgery procedures will not treat is presbyopia, the
3 gradual age related condition of suddenly fuzzy print
4 and the necessity of reading glasses. When a person
5 reaches a certain age (around 40), the eyes start to
6 lose their capability to focus sharply for near
7 vision. Presbyopia is not due to the cornea but comes
8 about as the lens loses its ability to accommodate or
9 focus sharply for near vision as a result of loss of
10 elasticity that is inevitable as people age.

11 Thermal lasers such as Ho:YAG have been proposed
12 for the correction of hyperopia by laser-induced
13 coagulation of the corneal. The present inventor has
14 also proposed the use of a laser-generated bifocal for
15 the treatment of presbyopic patients but fundamental
16 issues caused by age of presbyopic patients still
17 remains unsolved in those prior approaches.

18 To treat presbyopic patients, or the reversal of
19 presbyopia, using the concept of expanding the sclera
20 by mechanical devices has been proposed by Schaker in
21 U.S. patents 5,529,076, 5,722,952, 5,465,737 and
22 5,354,331. These mechanical approaches have the
23 drawbacks of complexity and are time consuming, costly
24 and have potential side effects. To treat presbyopia,
25 the Schaker patents Nos. 5,529,076 and 5,722,952
26 propose the use of heat or radiation on the corneal
27 epithelium to arrest the growth of the crystalline
28 lens and also propose the use of lasers to ablate
29 portions of the thickness of the sclera. However,
30 these prior arts do not present any details or
31 practical methods or laser parameters for the
32 presbyopic corrections. No clinical studies have been
33 practiced to show the effectiveness of the proposed
34 concepts. The concepts proposed in the Schaker

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1 patents regarding lasers suitable for expanding the
2 sclera tissues were incorrect in that the proposed
3 lasers did not identify those which are "cold lasers"
4 and can only conduct the tissue ablation rather than
5 thermal burning of the cornea. Furthermore, the
6 clinical issues, such as accuracy of the sclera tissue
7 removal and potential tissue bleeding during the
8 procedures, were not indicated in these prior patents.

9 In addition, it is essential to use a scanning laser
10 to achieve the desired ablation pattern and to control
11 the ablation depth on the sclera tissue.

12 One objective of the present invention is to
13 provide an apparatus and method to obviate these
14 drawbacks in the above Schaker patents.

15 It is yet another objective of the present
16 invention to provide an apparatus and method which
17 provide the well-defined laser parameters for
18 efficient and accurate sclera expansion for
19 presbyopia reversal and the treatment and preventing
20 of open angle glaucoma.

21 It is yet another objective of the present
22 invention to use a scanning device such that the
23 degree of ciliary ~~muscle~~ ^{muscle} accommodation can be
24 controlled by the location, size and shapes of the
25 removed sclera tissue.

26 It is yet another objective of the present
27 invention to define the non-thermal lasers for
28 efficient tissue ablation and thermal lasers for
29 tissue coagulation. This system is able to perform
30 both in an ablation mode and in a coagulation mode for
31 optimum clinical outcomes. It is yet another
32 objective of the present invention to provide an
33 integrated system in which dual-beam lasers can be
34 scanned over the corneal surface for accurate ablation

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1 of the sclera tissue without bleeding, with ablation
2 and coagulation laser beams simultaneously applied on
3 the cornea.

4 It is yet another objective of the present
5 invention to define the optimal laser parameters and
6 the ablation patterns for best clinical outcome for
7 presbyopia patients, where sclera expansion will
8 increase the accommodation of the ciliary ~~muscle~~ ^{muscle}

9 It is yet another objective of the present
10 invention to provide the appropriate scanning patterns
11 which will cause effective sclera expansion.

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13 SUMMARY OF THE INVENTION

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15 The preferred embodiments of the present surgical
16 laser consists of a combination of an ablative-type
17 laser and a coagulative-type laser. The ablative-type
18 laser has a wavelength range of from 0.15 to 0.35
19 microns and from 2.6 to 3.2 microns and is operated in
20 a Q-switch mode such that the thermal damage of the
21 corneal tissue is minimized. The coagulative-type
22 lasers includes a thermal laser having a wavelength of
23 between 0.45 and 0.9 microns and between 1.5 and 3.2
24 microns, and between 9 and 12 microns operated at a
25 long-pulse or continuous-wave mode.

26 It is yet another preferred embodiment of the
27 present invention to provide a scanning mechanism to
28 effectively ablate the sclera tissue at a controlled
29 depth by beam overlapping.

30 It is yet another preferred embodiments of the
31 present invention to provide an apparatus and method
32 such that both the ablative and the coagulative lasers
33 can have applied to their beams the corneal surface to
34 thereby prevent bleeding during the procedure.

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1 It is yet another embodiment of the present
2 invention to provide an integration system in which a
3 coagulative laser may have the beam delivered by a
4 scan or by a fiber-coupled device which can be
5 manually scanned over the cornea. It is yet another
6 embodiment of the present invention to focus the laser
7 beams in a small circular spot or a line pattern.

8 It is yet another embodiment of the present
9 invention to provide a coagulative laser to prevent
10 the sclera tissue bleeding when a diamond knife is
11 used for the incision of the sclera.

12 It is yet another embodiment of the present
13 invention to use a metal mask on the corneal surface
14 to generate a small slit when the laser is scanning
15 over the mask. In this embodiment, the exact laser
16 spot size and its propagating stability are not
17 critical.

18 It is yet another embodiment of the present
19 invention to provide an integration system in which
20 the sclera expansion leads to the increase of the
21 accommodation of the ciliary muscle for the treatment
22 of presbyopia and the prevention of open angle
23 glaucoma.

24 Further preferred embodiments of the present
25 invention will become apparent from the description of
26 the invention which follows.

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28 BRIEF DESCRIPTION OF THE DRAWINGS

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30 Figure 1 is a block diagram of an integrated
31 laser system consisting of two lasers of different
32 wavelengths coupled to the cornea by mirrors and a
33 scanning device;

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Figure 2 is a block diagram of a laser system where the coagulative laser is fiber-coupled and manually delivered to the cornea;

Figure 3 is the schematic drawing of the anteroposterior section through the anterior portion of a human eye, where the sclera and ciliary muscle are shown; and

Figures 4A-4D are diagrams of the possible ablation patterns which will achieve a presbyopia-reversal.

DETAILED DESCRIPTION OF THE INVENTION AND THE
PREFERRED EMBODIMENTS

Figure 1 of the drawings is a schematic of a laser system having an ablative laser 1 producing a laser beam 2 of a predetermined wavelength and focused by a lens 3 onto a reflecting mirror 4 which is coupled to another reflecting mirror 5. The system also consists of a coagulation laser 6 having a laser beam 7 of a predetermined wavelength focused by a lens 3A through a mirror 5. The ablation laser 1 beam 2 and the coagulation laser 6 beam 7 are directed onto a scanner 8. The beams 2 and 7 are then reflected by a mirror 9 onto the cornea 10 of a patient's eye. The scanner 8 consists of a pair of motorized coated mirrors with a 45 degree highly reflecting both the ablative laser beam 2 and the coagulative laser beam 7. The mirror 4 and mirror 9 are highly reflective to the wavelength of the beams 2 and 7. Mirror 5 is coated such that it is highly reflective of laser beam 2 but highly transparent to laser beam 7. The focusing lens 3 has a focal length of about 10-100 cm such that the spot size of the ablative laser beam 2 is about 0.1-0.8 mm on the corneal surface. The

1 focusing lens 3A also has a focal length about 10-100
2 cm such that the spot size of the coagulative laser
3 beam 7 is about 0.2-2.0 mm on the corneal surface. In
4 Figure 1, both the ablative and the coagulative lasers
5 beams 2 and 7 are scanned by the scanner 8 over the
6 corneal sclera area of the eye 10 to generate
7 predetermined patterns, as shown in Figure 4. In
8 Figure 1, the said coagulative laser 6 is used to
9 prevent the potential bleeding during the ablation
10 process of the sclera tissue. Typically, the
11 coagulative laser 6 beam 7 has a spot size larger than
12 the ablative laser 1 beam 2 and has an average power
13 in the range of 20-3000 mW, depending upon the size of
14 the focused beam. To achieve an effective
15 coagulation, the temperature increase of the sclera
16 tissue produced by the coagulative laser beam 7 should
17 be in the range of 40-70 degree Centigrade. The
18 preferred embodiment of the laser 1 and 6 includes a
19 pulsed ablative laser with a pulse width less than 200
20 nanoseconds such as a Er:YAG laser; Er:YSGG laser; an
21 optical parametric oscillation (OPO) at 2.6-3.2
22 microns; a gas laser with a wavelength of 2.6-3.2
23 microns; an excimer laser of ArF at 193 nm; a XeCl
24 laser at 308 nm; a frequency-shifted solid state laser
25 at 0.15 - 3.2 microns; a CO laser at about 6.0 microns
26 and a carbon dioxide laser at 10.6 microns. The long
27 pulse coagulative lasers have a pulse longer than 200
28 nanoseconds of a green laser; or an argon laser; or a
29 Ho:YAG at 2.1 microns; or a Er:glass at 1.54 microns;
30 or an Er:YAG; or an Er:YSGG; or a diode laser at 0.8-
31 2.1 microns, or any other gas lasers at 0.8-10.6
32 microns. To achieve the ablation of the sclera tissue
33 at the preferred laser spot size of 0.1-0.8 mm
34 requires an ablative laser energy per pulse of about

1 0.1-5.0 mJ depending on the pulse duration. On the
 2 other hand, the coagulative laser should have an
 3 average power of about 30 mW for a small spot and
 4 about to 3 W for a larger spot.

5 Referring to Figure 2, an alternative schematic
 6 for the coagulative laser 6 is coupled to a fiber 11
 7 for delivery of the beam to the cornea, where a line
 8 pattern may be performed by manually scanning the beam
 9 over the cornea. Alternatively, a fiber-coupled
 10 coagulation laser 6 may be focused by a cylinder lens
 11 to form a line spot on the cornea where a typical spot
 12 size of 0.2-2.0 mm x 3.0 -5.0 mm is preferred. In
 13 Figure 2, the ablative laser 1 has the same schematic
 14 as that of Figure 1 where the laser beam 2 is coupled
 15 to the scanner 8 and reflected by the mirror 9 onto
 16 the cornea. An alternative embodiment of the present
 17 invention is to use a cylinder lens to focus the
 18 ablative laser 1 to a line spot with a size of 0.1-0.8
 19 mm x 3.0 - 5.0 mm on the corneal surface to eliminate
 20 the scanner 8. Another embodiment may use an optical
 21 fiber or an articulate arm to deliver both the
 22 coagulative and ablative laser beams such that the
 23 presbyopia treatment may be conducted manually without
 24 the need of a scanner or reflecting mirrors.

25 Figure 3 shows the lens of a human eye 12
 26 connected to the ^{sclera 13 and ciliary body 14} ~~ciliary body 13~~ and the sclera 14 by
 27 zonule fibers 15. Expansion of the sclera ¹³ ~~14~~ will
 28 cause the ciliary muscle to contract and the lens
 29 becomes more spherical in topography with a shorter
 30 radii of curvature for near objects. The reversed
 31 process of ciliary muscle relaxation will cause a
 32 longer radii of curvature for distant objects.
 33 Therefore, laser ablation of the sclera tissue will
 34 increase the accommodation of the ciliary body for the

1 presbyopic patient to see both near and distance. For
2 efficient sclera expansion, the depth of the laser
3 ablation needs to be approximately 80% - 90% of the
4 sclera thickness which is about 500 - 700 microns.
5 For safety reasons, the ablation depth should not cut
6 through the choroid. It is therefore clinically
7 important that the patient's sclera thickness be
8 measured pre-operatively and the laser ablation depth
9 controlled. A scanning laser is used to control this
10 depth by the number of scanning lines or slots over
11 the selected area at a given set of laser parameters.
12 Pre-operatively, PMMA is used to calibrate the depth
13 of tissue ablation. Alternatively, the surgeon may
14 observe the color change of the ablated sclera tissue
15 to determine when the ablation depth reaches the
16 interface of the sclera and the ciliary.

17 Figure 4 shows examples of ablation patterns
18 which will cause sclera expansion and increase the
19 accommodation of the presbyopic patient. As shown in
20 Figure 4A, line patterns are conducted between
21 circles 16 and 17 which have diameters of about 8-11
22 mm and 12-15 mm, respectively. The width of the
23 ablated lines are about 0.1-0.5 mm with a depth of
24 80%-90% of the sclera. Eight (8) lines are shown in
25 Figure 4A as an example but it can be more or less
26 without departing from the spirit and scope of the
27 invention. Enhancement may be performed by adding
28 more ablation lines. Figure 4B shows a ring pattern
29 with a diameter 18 of about 12-14 mm. A two-ring
30 pattern 19 is shown in Figure 4C where two circles
31 have diameters of about 10 mm and 12 mm, respectively.
32 Another example of an ablation pattern is shown in
33 Figure 4D where the ablation laser is focused to a
34 round spot 20 of about 0.1-0.5 mm in diameter and

1 scanned over the sclera area to form an eight spot
2 symmetric ring which has a diameter of about 12-14 mm.
3 In all the above described ablative patterns, the
4 coagulative laser described in Figures 1 and 2
5 simultaneously deliver these patterns such that the
6 sclera tissue may be coagulated as the tissue is being
7 ablated. The preferred spot sizes of the coagulative
8 lasers are larger than that of the ablative laser so
9 that the alignment of the coagulative laser is not
10 critical.

11 Another embodiment of controlling the ablation
12 area of the sclera area is to use a metal mask which
13 has a plurality of slits each having an approximate
14 dimension of 0.1-0.3 mm x 3.0-5.0 mm. Both of the
15 ablative and coagulative lasers will scan over the
16 mask which is placed on the corneal surface to
17 generate the desired slit pattern on the sclera. In
18 this embodiment using a mask, the small laser spot
19 sizes of 0.1 mm, which may be difficult to achieve,
20 are not needed in order to generate the slit size on
21 the cornea. Laser spot sizes of 0.2-1.0 mm will
22 generate the desired ablation dimension on the sclera
23 after scanning over the mask. Furthermore, the
24 embodiment of using a mask will not require a precise
25 stability of the laser beam path onto the corneal
26 surface. Without using a mask, both the exact laser
27 beam spot size and its stability in propagating would
28 be essential.

29 Another embodiment of sclera expansion of the
30 present invention is to use diamond knife for the
31 incision of the sclera tissue in the patterns
32 described in Figures 4A, 4B and 4C where the
33 coagulation laser is simultaneously applied onto the
34 cut tissue to prevent bleeding. The incision depth

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1 should be about 80% to 90% of the sclera thickness in
2 order to achieve the effects of sclera expansion.
3 Accordingly, the pre-operative measurement of the
4 sclera thickness is essential for the knife incision
5 procedure and surgeon's skill is more important than
6 that of using an ablative laser, in which the ablation
7 depth of the sclera tissue is well controlled by the
8 numbers of scanning lines in a given pattern. We are
9 able to calibrate the ablation rate of various lasers
10 on the sclera tissue by comparing the clinical data
11 and that of the selected materials including a PMMA
12 plastic sheet.

13 The invention having now been fully described, it
14 should be understood that it may be embodied in other
15 specific forms or variations without departing from
16 the spirit or essential characteristics of the present
17 invention. Accordingly, the embodiments described
18 herein are to be considered to be illustrative and not
19 restrictive.